

Docket No.: 658312001000
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Kevin P. CONNORS et al.

Application No.: 10/789,139

Confirmation No.: 9270

Filed: February 27, 2004

Art Unit: 3769

For: SYSTEM AND METHOD FOR HEATING
SKIN USING LIGHT TO PROVIDE TISSUE
TREATMENT

Examiner: David M. Shay

DECLARATION OF SCOTT A. DAVENPORT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Scott A. DAVENPORT declare as follows:

1. I am currently the Vice-President of Research and Development at Cutera. I have been employed by Cutera since 2003.
2. Cutera sells light based systems for treatment of various dermatological conditions. The first product that was developed at Cutera was an Nd:YAG laser system. This laser based system is used for hair removal and treating certain vascular conditions.
3. Cutera then developed a flashlamp based product. This product now includes a few variants with different treatment parameters and is used for hair removal, certain vascular procedures and skin rejuvenation.
4. After developing its first two products, Cutera began to develop a product for tightening the skin. In order to tighten the skin, one needs to heat the collagen in the dermis a sufficient amount to change its character. The collagen will then shrink or remodel in a manner to produce the appearance of a general tightening of the skin. Our

goal was to develop a product which could create a tightening of the skin in a uniform, aesthetically pleasing manner, which would cause minimal pain and downtime for the patient and be easy for physicians to use.

5. The initial development work included determining the optimal wavelength range that could be used for this treatment. We believed that infrared wavelengths were preferred because they have little melanin or hemoglobin absorption and less scattering in tissue than shorter wavelengths. In particular wavelengths above 1050nm to 1850nm were of primary interest. Conventional non-laser light sources used in the dermatology industry up to this point were flashlamps, which have the limitation of outputting mainly visible wavelengths, with the intensity of the infrared output above about 1200nm begin relatively low.

6. To achieve our goal, we needed to develop a new light source approach. We settled on a custom tungsten halogen bulb with appropriate filtering. First, we used a 1050 nm long-pass filter to block out all wavelengths shorter than 1050nm. It was also determined that radiation having high levels of water absorption would be too superficially absorbed in tissue. Above 1050 nm the water absorption is dominated first by an absorptive band centered around 1450nm, then increasing absorption above 1800-1850nm. We accomplished filtering longer wavelength bands by use of a water filter, consisting of a tube of flowing water placed around the lamp. The lamp itself also generated reduced intensities over about 1800nm. The two filtering approaches coupled with the optimized custom lamp produced an output in the 1050nm to 1850nm wavelength band. This band achieved the desired result of tissue heating from 1-3.5mm deep.

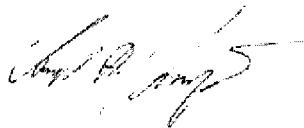
7. I am not aware of any prior art device which used a light source having an output wavelength between 1050nm and 1850nm and configured to generate long pulses of broadband light for skin tightening. Moreover, our design decisions, including selecting the lamp, selecting the appropriate wavelength range, and selecting the treatment parameters occurred only after significant modeling and experimentation and in my opinion, these choices were not obvious in view of the earlier systems of which I was aware.

8. In 2004, Cutera commercially released its Titan treatment system. The Titan handpiece includes a filtered filament light source generating an output in the 1050 to 1850nm range. The device is used for tightening the skin of patients, primarily around the face, neck and abdomen. The handpiece includes a sapphire cooling plate which is placed in contact with the tissue. The lamp is typically energized for about two seconds for each treatment.

9. The Titan handpiece is sold for connection to a console having a control system and a power supply. When purchased as a complete system (handpiece, control system and power supply) the selling price is about \$90,000. A customer that previously purchased certain laser or flashlamp systems from Cutera (which included a suitable controller and power supply) can upgrade to include Titan capabilities for about \$50,000. To date, Cutera has sold more than 3500 complete Titan systems, upgrades and refills (lamp replacement and refurbish) for a composite revenue of more than 60 million dollars. The successful sales of this handpiece is directly attributable to the claimed design parameters.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 4/22/09



Scott A. Davenport